AdventHealth

POLICY

Policy #	Policy Name
CW AHC 110	Legally Authorized Representatives, Children, and Guardians in Research
Policy Location	**Responsible Department**
*Company-Wide Policies	Research Services
Policy Owner or Executive Owner	**Original Creation Date**
Executive Director Research Services	01/18/2022
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06/15/2022	06/04/2024

I. **SCOPE:** This policy applies to all employees and agents of AdventHealth, conducting human subjects research involving adults lacking capacity or children.

II. **PURPOSE:** This policy describes the AdventHealth's determination of which individuals are Legally Authorized Representatives (LARs), Children, and Guardians.

III. **POLICY:**

A. Florida

1. Adults - A LAR may consent to an adult individual participating in research, where that adult individual is not competent by reason of mental incapacity, if the research is approved by an IRB in conformance with federal regulations governing human subject protection. The following individuals are LARs, in the following order of priority:
   a) A health care surrogate designated in writing by the individual (when the individual was competent), which designation was witnessed by two adult witnesses
   b) A judicially appointed Guardian or guardian advocate of the person having a developmental disability, who has been appointed pursuant to Fla. Stat. Title XLIII, Chapter 744, who has been authorized to consent to medical treatment
   c) A proxy designated pursuant to Florida law, in the following order of priority:
      i. Patient's spouse
      ii. An adult child or, if the patient has more than one adult child, a majority of the adult children who are reasonably available for consultation
      iii. A parent of the individual
      iv. The adult sibling or, if the individual has more than one sibling, a majority of the adult siblings who are reasonably available for consultation
      v. An adult relative of the individual who has exhibited special care and concern for the individual and who has maintained regular contact with the individual and is familiar with the individual's activities, health and religious and moral beliefs
      vi. A close friend of the individual who has exhibited special care and concern for the individual and who presents an affidavit stating that he or she is a friend

of the individual, is willing and able to become involved in the individual's health care and has maintained such regular contact with the individual so as to be familiar with the individual's activities, health and religious and moral beliefs.

vii. A clinical social worker selected in accordance with Florida statutes.

2. Children - A LAR may consent to Children participating in research, only where the LAR is a parent or Guardian. Individuals who can document that they are legally authorized to consent on behalf of the child to general medical care may serve as a Guardian. Before obtaining permission for a child to take part in research from someone who is not a parent, contact legal counsel. Individuals under the age of 18 years are Children with the exception of:
   a) Minors 16 or older who have had the disability of nonage removed by a circuit court
   b) Minors who are married or have been married (including minors whose marriage is dissolved or who is widowed)
   c) Unwed pregnant minors to the extent the research is related to such minor's pregnancy
   d) Minors adjudicated as an adult and in the custody or under the direct supervision of the Department of Corrections, except in regard to medical services related to abortion or sterilization

B. Georgia

1. Adults
   a) When an adult lacks the capacity to consent, only a LAR for that adult can give consent for participation in research, unless the IRB has waived the requirement to obtain informed consent.
   b) When research will be conducted in Georgia, a LAR includes a person appointed as a health care agent under a power of attorney for health care or other appropriate legal document, or a court appointed Guardian of the person. In the absence of an appointed individual, then the following may provide consent in the following order of priority:
      a) Spouse
      b) Any adult offspring for their parents
      c) Any parent for their adult offspring
      d) Any adult for their adult sibling
      e) Any grandparent for their adult grandchild
      f) Any adult grandchild for their grandparent
      g) Any adult niece, nephew, aunt, or uncle related in the first degree
      h) In the absence of any other person authorized to provide consent, the IRB may consider allowing an adult close friend of the prospective subject to provide consent. An "adult close friend" is an adult who has exhibited special care and concern for the subject, who is generally familiar with the subject's views and desires, and who is willing and able to act in the patient's best interest.

2. Children
   a) Under Georgia law, an unemancipated person under the age of 18 years is considered a child. A child is emancipated under Georgia law (and therefore capable of providing his or her own consent) if the child is 16 or 17 years of age and:
      i. is legally married
      ii. is on active duty with the U.S. Armed Forces
      iii. has obtained an emancipation order from a court
   b) When research will involve an unemancipated child, a permission must be obtained from the child's parent or Guardian, unless the IRB has waived this requirement.
   c) Georgia law will control research conducted in Georgia. Under Georgia law, a Guardian may be appointed by the court; the power of a legally appointed Guardian is the same as that of a parent over a child, with the Guardian standing in place of the parent, unless the court order appointing the Guardian specifically states otherwise.

C. Illinois

1. Adults - Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a LAR. When research is conducted in Illinois, the following individuals meet this definition:
   a) When experimental treatment is being provided to an adult patient who does not have capacity to make her or his own medical decisions, consent may be obtained from the following LARs in order of priority:
      i. The court appointed Guardian of the person if that Guardian has the right to make healthcare decisions.
      ii. The agent under a durable power of attorney for healthcare.
      iii. A surrogate under the Healthcare Surrogate Act, in the following order:
         - the patient's guardian of the person;
         - the patient's spouse;
         - any adult son or daughter of the patient;
         - either parent of the patient;
         - any adult brother or sister of the patient;
         - any adult grandchild of the patient;
         - a close friend of the patient;
         - the patient's guardian of the estate;
         - the patient's temporary custodian appointed under subsection (2) of Section 2-10 of the Juvenile Court Act of 1987 if the court has entered an order granting such authority pursuant to subsection (12) of Section 2-10 of the Juvenile Court Act of 1987.
   b) For other research studies involving adults unable to consent, permission must be sought from the priority list above.

2. Children - DHHS and FDA Subpart D applies to all research involving Children.

a) When research is conducted in Illinois all individuals under the age of 18 years are generally considered to be minors.
b) Unless the IRB has waived the requirement to obtain consent, when research involves Children, consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care. Before obtaining permission for an individual who is not a parent, contact legal counsel.

D. Kansas

1. Adults - If a patient lacks legal capacity to make or communicate decisions, a health care agent, legally designated by a patient, may consent, on the patient's behalf, to any care, treatment, or service. A health care agent is most often identified in a durable power of attorney for healthcare decisions (DPOA).
   a) When a patient does not have a health care agent, any person who has been appointed by a court as the Guardian of a patient may authorize any care, treatment or service on behalf of the patient.
      i. If the patient has executed a DPOA for Healthcare and thereafter a court appoints a Guardian, the Guardian has the same power to revoke or amend the DPOA for Health Care as the patient would have had if the patient were not disabled or lacked decisional capacity.
      ii. However, the Guardian may not consent to the withholding or withdrawal of life-sustaining treatment unless the Guardian has specific approval of the court to do so or the Guardian is acting pursuant to an advance directive made by the person before the person became disabled or lacked decisional capacity.
   b) If a patient is not competent and does not have a health care agent, Guardian or advance directive, a physician may obtain "assent" from the patient's family members or adults who are most involved with the patient and most knowledgeable about the patient's personal values and preferences concerning the performance of any care, treatment, or service on the patient.
      i. At all times, regardless of "assent," the physician must act in the best interest of the patient.
      ii. If there is serious disagreement between the patient's family members or adults who are most involved with the patient, or in the event that no such person may be found, administration, and in some cases, legal counsel should be contacted in determining treatment and care of an incapacitated person where no person is legally authorized to consent.
2. Children - A parent, Guardian, or other appropriate decision-maker, must give consent prior to performing any care, treatment, or service on an unemancipated minor, unless otherwise permitted by law. Minors are deemed emancipated if they are sixteen (16) years old and are or have been married, or if a district court has declared them emancipated. If the minor has been removed from their Parents' custody, either temporarily or permanently, the following entities may consent on behalf of the child:

a) Where the minor has been committed to the custody of the Department of Children and Families ("DCF") because the parental rights have been severed or where a court has so authorized, the secretary of DCF, or their designee, may consent to the minor's medical treatment
b) Where a petition has been filed with the court pursuant to K.S.A. § 38-2201 et. seq. (the Revised Kansas Code for Care of Children) alleging that the minor is a "child in need of care," the court may consent to medical treatment of the minor. Additionally, prior to the court's adjudication of the petition, the person having "custody" of the minor ("custodian"), or the custodian's agent, may not consent to participation in an experimental procedure, unless an institutional review board or review committee reviews and approves the experiment in advance. For purposes of this section, "custody" means the status created by a court order, whether temporary protective or legal, which vests in an individual or agency, the right to the physical possession of the child. A "child in need of care" includes a minor who is neglected, abused, abandoned, a run-away, or who is before the court for committing certain crimes.

E. Kentucky

1. Adults **-** Consistent with Kentucky health care decision statutes for choosing a LAR for adult subjects unable to consent, one of the following responsible parties, in the following order of priority (if no individual in a prior class is reasonably available, willing, and competent to act), is authorized to make research participation decisions on behalf of the person:
   a) the judicially appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship
   b) the attorney-in-fact named in a durable power of attorney, if the durable power of attorney specifically includes authority for the decisions to be made under the consent
   c) the spouse of the person
   d) an adult child of the person, or if the person has more than one (1) child, the majority of the adult children who are reasonably available for consultation
   e) the parents of the person
   f) the nearest living relative, or if more than one of the same relation, a majority of the nearest living relatives
2. Children - Consistent with Kentucky health care decision statutes for choosing an LAR for children, the following responsible parties in the order of priority listed shall be authorized to make research participation decisions on behalf of the child:
   a) the judicially appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship
   b) the parent of the child
   c) Individuals under the age of 18 years are Children with the exception of emancipated individuals

i. Absent a court order, there are no classes of individuals under the age of 18 who are named as emancipated for all purposes.
ii. Emancipated individuals are individuals under the age of 18 who are living on their own, have borne a child, or are married are viewed as emancipated and are able to consent to participate in some research studies.
   - Legal counsel must review the studies on a case-by-case basis to determine whether the subjects are legally emancipated.
   - If pregnant individuals under the age of 18 are neither married nor living on their own (i.e., living at home under the care of their parents or some other adult), they are not legally emancipated, and both parental permission and subject assent are needed.
   - If a child or a class of subjects is deemed to be emancipated, 45 CFR 46 Subpart D and 21 CFR 50 Subpart D do not apply, and the subject may provide informed consent as an adult.

3. Consent by a LAR should involve all the same considerations that informed consent from a competent subject involves.
4. In Kentucky, a Guardian is an individual who may serve as a LAR as defined above and meet the federal definitions for a Guardian.

F. North Carolina

1. Adults - When an adult lacks the capacity to consent, a LAR for that adult can give consent for participation in research
   a) In accordance with North Carolina law and policies regarding informed consent for medical treatment, the order of authority to provide consent as a LAR on behalf of an adult subject who lacks the capacity to consent, for participation in clinical research is as follows:
      i. Court-approved guardian
      ii. Health care agent
      iii. Durable general power of attorney
      iv. Spouse
      v. Adult offspring for their parents
      vi. Parent for their adult offspring
      vii. Adult sibling
      viii. Uncle and/or aunt
      ix. Other adult relative
   b) In addition to requiring that LAR consent be provided according to the above hierarchy, approval of a proposal for LAR consent in research that is not clearly therapeutic in nature will require demonstration of the fact that
      i. the research involves no more than minimal risk to the subject
      ii. the research can only be performed through the enrollment of subjects whose consent must be provided by an LAR
      iii. the LAR has confirmed through IRB-approved language in the consent form that he or she has no conflict of interest in acting on behalf of the subject.

2. Children – A parent or Guardian, must give consent prior to performing any care, treatment, or service on Children.
   a) Under North Carolina law, a Guardian of a child must be appointed by a court under Article 6 of Chapter 35A of the North Carolina General Statutes.
   b) Exceptions - North Carolina law defines individuals less than 18 years of age to be minors (and thus Children as defined in federal regulation), and federal regulations applies unless the minor:
      i. Has been declared by a court order to be emancipated
      ii. Has been legally married
      iii. Is serving in the armed forces of the United States
   c) Additionally, there are four medical conditions described in North Carolina law for which a minor may seek medical care for the prevention, diagnosis or treatment of the medical condition, and thus give informed consent for this medical care. These medical conditions are:
      i. Sexually transmitted diseases and other reportable diseases
      ii. Pregnancy
      iii. Abuse of a controlled substance or alcohol
      iv. Emotional disorders or mental health treatment

G. For research outside Florida, Georgia, Illinois, Kentucky, Kansas, or North Carolina, legal counsel must be engaged to determine which individuals are Legally Authorized Representatives, Children, or Guardians.

IV. PROCEDURE/GUIDELINES: N/A

V. DEFINITION(S): For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

VI. EXCEPTION(S): See CW AHC 101 Research Oversight

VII. REFERENCE(S):

Fla. Stat. Title XLIII, Chapter 744
755 ILCS 40/ - Health Care Surrogate Act
45 CFR 46 Subpart D
21 CFR 50 Subpart D

VIII. RELATED DOCUMENT(S) / ATTACHMENT(S):

- Forms: 950-0059: Close Personal Friend Affidavit. Florida
- CW AHC 101 Research Oversight
- CW AHC 107 Definitions in Human Research
- CW AHC 108 Human Research Protection Program
- CW AHC 112 Investigator Obligations in Research